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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,872	05/19/2006	Ilia Fishbein	RCHP-135US	1203

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EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
05/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,872	FISHBEIN ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2,4-6 and 11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application 10/567,872 is a 371 of PCT/US04/26509 filed on 08/13/2004, which claims benefit of 60/494,886 filed on 08/13/2003.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1, 3, 7-10, drawn to a composition comprising a surface and a modified protein, wherein the modified protein is covalently bound to the surface, in the reply filed on 02/21/2008 is acknowledged. The traversal is on the ground(s) that (i) Claims 1, 3, 7, 8-10 and 17-32 do not merely share "a surface covalently bound to a modified protein," as the Office Action states on page 5. Rather, the common feature in all groups is the entire composition of claim 1. Therefore, claims 1, 3, 7, 8-10, and 17-32 are so linked as to form a single general inventive concept under PCT Rules 13.1 and 13.2.; (ii) Claims 1, 3, 7, and 8-10 are drawn to a composition comprising a modified protein covalently bound to a surface; (iii) Claims 17- 31 are drawn to a special process for preparing the composition of claim 1, including special methods of modifying the protein, treating the surface, and reacting the modified protein with the treated surface; and claim 32 is drawn to a special process of using the composition of claim 1 to deliver a viral vector to an animal tissue. Therefore, claims 1, 3, 7, 8-10, and 17-32 have unity of invention and should be prosecuted concurrently. This is not found persuasive because as stated in the Restriction requirement mailed on 02/12/2008, Group I and Group II are drawn to patentably distinct products and Groups III-VI are drawn to patentably different methods. The only common technical feature in all groups as a surface covalently bound to a modified protein. The arguments that the common feature in all groups is the entire

composition of claim 1 are found not persuasive because a gene transfer vector recited in claim 1 is optional for the composition, which set forth two distinct compositions of Group I and Group II. The only recited element of the composition of Group I is "a surface covalently bound to a modified protein" as stated on page 5 of the Restriction requirement dated 11/08/2007.

Claims 2, 4-6, and 11-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 1-32 are pending. Claims 1, 3, 7-10 are currently under examination.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Sharma et al. (Sharma et al., Study of protein splicing and intein-mediated peptide bond cleavage under high-

cell-density conditions. *Biotechnol Prog.* 19(3): 1085-90, 2003; This reference is cited on pages 5 of Restriction requirement dated 11/08/2007).

Claim 1 is drawn to a composition comprising a surface and a modified protein covalently bound to the surface. Claim 3 limits the modified protein being covalently bound to the surface through a thiol residue (i.e. -SH functional group) and a linker.

Sharma et al. teaches that an intein fusion protein consists of the modified intein fused between a target protein and an affinity tag, and the affinity tag allows the fusion protein to be immobilized on the surface of an affinity matrix while other proteins are washed off the column. The intein catalyzes the cleavage reaction at the junction between the target protein and the intein terminus in the presence of a thiol reagent such as dithiothreitol (DTT), which reduces S-S bond to -SH functional group (See Figure 1, page 1086, Sharma et al. et al., Study of protein splicing and intein-mediated peptide bond cleavage under high-cell-density conditions. *Biotechnol Prog.* 19(3): 1085-90, 2003).

Thus, Sharma et al. clearly anticipate claims 1 and 3 of instant application.

3. Claims 1, 3, 7, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Halbreich et al. (U.S. patent No. 6,150,181, issued Nov. 21, 2000).

Claim 1 is drawn to a composition comprising a surface and a modified protein covalently bound to the surface. Claim 3 limits the modified protein being covalently bound to the surface through a thiol residue (i.e. -SH functional group) and a linker. Claim 7 limits the surface being a metal surface. Claim 8 limits the metal surface being a surface of a medical

device. Claim 10 further limits claim 8 to the medical device being at least one of an internal device and an external device.

Halbreich et al. teaches magnetic nano-particles (mean diameter 9 nm) named ferrofluid (FF), which is made of the ferrites MFe_2O_4 (including magnetite Fe_3O_4) and maghemite γ Fe_2O_3 (which is encompassed by the limitation, metal surface, recited in claim 7 of instant application), and the surface of the magnetic nano-particles are coated/coupled with an effector protein, including recombinant protein annexine (Anx) V and an antibody of interest. The coupling between magnetic nano-particles and effector protein of interest is achieved by the use of difunctional compounds (i.e. cross linkers) such as N-succinimdyl 3-(2-pyridyldithio) propionate (SPDP), which make it possible to bond an effector protein to the particles via a peptide bond and a disulfide bridge (S-S) (which is encompassed by the limitation, a thiol residue and a linker, recited in claim 3 of instant application), without damage to the protein (See lines 38-40, column 1, and lines 2-7, 33-50, column 2, Halbreich et al., 2000), which is encompassed by the limitation modified protein recited in claim 1 of instant application.

Claim 8 is rejected because Halbreich et al. teaches using Anx FF (i.e. annexine covalently linked to ferrofluid nano-particles) as a medical device to analyze the retention of erythrocytes (i.e. formation of erythrocyte-Anx FF complex) in the blood samples of patients (See Figure 5, and Table 1 in column 10, Halbreich et al., 2000).

Claim 10 is rejected because the magnetic nano-particles Anx FF used for analysis of the retention of erythrocytes in the blood samples of patients, taught by Halbreich et al., are considered as an external medical device (when blood is taken out of a patient) and/or an internal medical device (when blood remains in a patient).

Thus, Halbreich et al. clearly anticipate claims 1, 3, 7, 8, and 10 of instant application.

4. Claims 1 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Feijen et al. (U.S. patent No. 4,634,762, issued Jan. 6, 1987).

Claim 1 is drawn to a composition comprising a surface and a modified protein covalently bound to the surface. Claim 7 limits the surface being a metal surface. Claim 8 further limits claim 7 to the metal surface being a surface of a medical device. Claim 9 further limits claim 8 to medical device selected from the group consisting of a stent, a heart valve, a wire suture, a joint replacement, a urinary dilator, an orthopedic dilator, a catheter, and an endotracheal tube. Claim 10 further limits claim 8 to the medical device being at least one of an internal device and an external device.

Feijen et al. teaches conjugates for coating a surface of a medical device and the conjugates are covalently bonded conjugates of an anticoagulant and protein that are prepared in the presence of a coupling agent that forms amide linkages between the anticoagulant and the protein. Feijen et al. teaches these conjugates are useful for enhancing the blood compatibility of certain surfaces of a prosthetic device (which is encompassed by internal device recited in claim 10 of instant application), a surgical apparatus, or an extra-corporeal medical device (which is encompassed by external device recited in claim 10 of instant application) (See abstract, Example 2, claim 18, Feijen et al. 1987). Feijen et al. teaches extra-corporeal medical device includes a catheter (which is encompassed by claims 7-9 of instant application) (See lines 24-38, column 4, Feijen et al.)

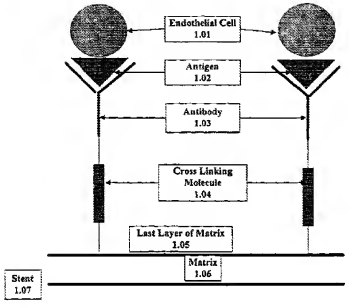
Thus, Feijen et al. clearly anticipate claims 1, and 7-10 of instant application.

5. Claims 1 and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kutryk et al. (U.S. patent No. 7,037,332, issued May 2, 2006, filed on 03/15/2001).

Claim 1 is drawn to a composition comprising a surface and a modified protein covalently bound to the surface. Claim 7 limits the surface being a metal surface. Claim 8 further limits claim 7 to the metal surface being a surface of a medical device. Claim 9 further limits claim 8 to medical device selected from the group consisting of a stent, a heart valve, a wire suture, a joint replacement, a urinary dilator, an orthopedic dilator, a catheter and an endotracheal tube. Claim 10 further limits claim 8 to the medical device being at least one of an internal device and an external device.

Kutryk et al. teaches a composition comprising a medical device coated with one or more antibodies and one or more layers of a matrix, and the matrix may be noncovalently or covalently attached to the medical device, and antibodies may be covalently attached to the matrix using hetero- or homobifunctional cross-linking reagents (See abstract, lines 1-4, column 5, lines 15-55, column 12, and Figure 1, Kutryk et al.).

Figure 1



Kutryk et al. teaches "medical device" refers to a device that is introduced temporarily or permanently into a mammal for the prophylaxis or therapy of a medical condition. These devices include any that are introduced subcutaneously, percutaneously or surgically to rest within an organ, tissue or lumen (which is encompassed by the limitation an internal device recited in claim 10). Medical devices may include, stents, synthetic grafts, artificial heart valves, permanent drug infusion catheters, embolic coils, embolic materials used in vascular embolization (e.g., PVA foams), and vascular sutures. (See lines 50-62, column 5, Kutryk et al.). Kutryk et al. also teaches using the medical device for endothelial cell binding assay, which is encompassed by the limitation an external device recited in claim 10 of instant application). Kutryk et al. further teaches that stents are composed of metallic structural elements onto which the matrix is applied (See lines 22-24, column 8, Kutryk et al.)

Thus, Kutryk et al. clearly anticipate claims 1 and 7-10 of instant application.

Conclusion

6. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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